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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,736	01/06/2004	Robert Vincent Martinez	31896-002000	2977
22204	7590	07/28/2005		
NIXON PEABODY, LLP 401 9TH STREET, NW SUITE 900 WASHINGTON, DC 20004-2128				
			EXAMINER YAO, LEI	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/751,736

Applicant(s)

MARTINEZ ET AL.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/5/05 11/16/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: exhibit A

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 17 (claims 1-8) and a species, polypeptide GPR49, SEQ ID NO: 84, as in the reply filed on 6/23/05 is acknowledged. The traversal is on the ground(s) that ten sequences constitute a reasonable number for examination.

Applicants argue that MPEP 803.04 states that it has been determined that normally ten sequences constitute a reasonable number for examination purposes and examiner's requirement to elect only one gene from Tables 1-5 is improper. Applicants also argue that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits. Applicant again disagrees that the contention that groups 1-837 are distinct or independent inventions since all the claims in 1-837 are directed to colon cancer genes and uses thereof.

These have been considered, but not found persuasive. The claims are drawn to a method of detecting a level of a polypeptide encoded by colon cancer genes listed in the tables 1-5.

Section 803.04 states:

"It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." It is noted that one sequence is included in the directive of "up to ten" sequences. However, the PTO does not have the computer resources to allow for the searching of more than one sequence per application.

Further the inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are drawn to a method of detecting a level of a polypeptide encoded by a gene listed in Table 1-5. The genes or gene products on the list have different chemical structures and the polypeptide may have different biological functions beyond than expressed in colon cancer conditions. The polypeptide may or may not play a role in the development of colon cancer or different colon cancer stages. Detecting the expression or the levels of the polypeptides require different method steps or modes of operation since the samples are collected from different

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biological sources of the colon cancer patients and also are from different colon cancer patient populations. Searching all genes and gene products with different SEQ ID Nos and searching the methods of detecting the expression of the genes in colon cancer tissues or other biological samples would impose a serious search burden. For reasons above, the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made **FINAL**.

Claims 1-20 are pending. Claims 9-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-8 will be examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/5/05 is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

Claim Objections

Claims 1-8 are objected to as being drawn to non-elected invention. Amendment of the claims indicating that colon cancer gene or gene product is GPR49 will obviate the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 8 are rejected as being vague and indefinite because of its reliance upon Tables within the specification; see MPEP (2173.05(s)).

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

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Therefore claims 4 and 8 are vague and indefinite for reference to Tables 1-5 and claims 4 and 8 also render the dependent claims 5-7 indefinite.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter rather than active steps. Section 706.03(a) of the M.P.E.P states that a scientific principle, divorced from any tangible structure, can be rejected as not within the statutory classes. O 'Reilly v. Morse, 56 U.S. (15 How.) 62 (1854). A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. See In re Warmerdam, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed.Cir. 1994). See also Schrader, 22 F.3d at 295, 30 USPQ2d at 1459.

Claims 1 and 7 are drawn to a method of detecting and comparing a level of a polypeptide encoded by a colon cancer gene to a control level of the polypeptide in a disease-free condition.

The outcome of comparing the level of a polypeptide encoded by colon cancer gene in a biological sample from subject to a normal control may be a plan or abstract idea for the colon cancer detection or colon cancer treatment, which may not be limited to a practical application. MPEP (2106) states "For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See Alappat, 33 F.3d at 1543, 31USPQ2d at 1556 57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578 79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114 19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine

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claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc))." The instant method claims recite the production of an abstract result, a mental step requiring only the comparison of two values. The claims do not dictate a final active method step directed to a practical application of the process, and therefore do not meet the requirements of 35 U.S.C. 101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Afar et al., (US Patent Application Publication, No, 2003/0232350, priority to Nov, 29, 2001) as evidenced by exhibit A.

Claims 1 is drawn to a method comprising of detecting a levels of a polypeptide encoded by a colon cancer gene in a biological sample of the subject and comparing the level of the polypeptide to a control, wherein the colon cancer gene is differentially expression in colon cancer tissues as compared to disease-free colon tissues. Claims 2-3 are further drawn to claim1, wherein the biological sample is a colon tissue, blood, or bodily wasted sample, and control level is an average level of polypeptide in the control sample of disease-free subjects, wherein the colon cancer gene is G-protein coupled receptor gene. Claims 4-6 are further drawn to claim 2, wherein the colon cancer gene is GPR49, SEQ ID NO: 84 and subject is colon cancer patient, who is subject to therapeutic treatment of the cancer. Claim 7 is drawn to detecting an expression profile of one or more colon cancer genes in a biological sample of a

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subject and comparing the expression profile to a control expression profile, wherein one or more colon cancer genes is differentially expressed in colon cancer tissues as compared to disease-free colon tissues. Claim 8 is further drawn to claim 1, wherein the colon cancer gene is GPR49, SEQ ID NO: 84.

Afar et al., disclose a method of diagnosing cancer including colon cancer by detecting the expression of genes including GPR49 as shown in protein sequence search in exhibit A. Afar et al., disclose that the differential expression of the gene is comparison of cancer tissues to the normal or non-cancer tissues (paragraph 68 and 69). Afar et al., also disclose that the biological samples are obtained from subjects having a treatment history or outcome history, which is subject to therapeutic treatment of the cancer (paragraph 19).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Glucksmann et al., (US Patent application publication, NO, 2001/0044130, Nov 2001).

Glucksmann et al., disclose a method of detecting differential expression of a G-protein-coupled receptor in normal colon (disease free colon tissue) and different differentiated colon cancer tissues (paragraph 35 and 38, figure 6 and 9). Glucksmann et al., also disclose that the biological samples include the tissues, cells and biological fluids isolated from patients or normal individuals (paragraph, 144). Glucksmann et al., further disclose that the differential expression of the G-protein-coupled receptor is determined by comparing the level of the protein expressed by the cells in colon cancer tissue to normal colon tissues and also disclose the expression of the protein by colon cancer tissue is up-regulated (figure 6).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

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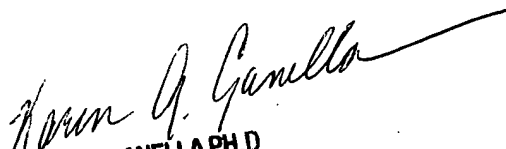
Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY


KAREN A. CANELLA PH.D.
PRIMARY EXAMINER

Wed Jul 13 13:55:06 2005

us-10-751-736-84.011.rapb

QY 241 LMYNNDDEPPTAIRTLNKEIGFHSNNIRSIPEKAFVGNPSLITTHFYDNPLOFVGRSA 300
DB 241 LMYNNDDEPPTAIRTLNKEIGFHSNNIRSIPEKAFVGNPSLITTHFYDNPLOFVGRSA 300
QY 301 FOHLPELRLTLNGASQITEPDLTGTANLESITLGAOISSLPQVCNQLPVLQVLDS 360
DB 301 FOHLPELRLTLNGASQITEPDLTGTANLESITLGAOISSLPQVCNQLPVLQVLDS 360
QY 361 YNLLEDLPSFSVCQKQKIDLRNNEYEKVDTFOQLSLRSNTLNMNKAIIHPNAFST 420
DB 361 YNLLEDLPSFSVCQKQKIDLRNNEYEKVDTFOQLSLRSNTLNMNKAIIHPNAFST 420
QY 421 LPSLITGLDSSNLSLSPITGLHGLTHLKLGTGNHALQSIISSNPPELVIEPVAVQCC 480
DB 421 LPSLITGLDSSNLSLSPITGLHGLTHLKLGTGNHALQSIISSNPPELVIEPVAVQCC 480
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DB 481 AFGVCENAYKISNQWKGDNSSMDLHKQDAGFQADREDDLEDFLDEEDLKALHSVQ 540
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DB 841 WTSKIPSLMSINSDDVEKOSCDSTOALVTFTSSSITTDLPSSVSPAPVTTESCLSS 900
QY 901 VAVFPCL 907
DB 901 VAVFPCL 907

Exhibit A

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Query Match 100.0%; Score 907; DB 15; Length 907;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 907; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Remaining Prior Application data removed - See File Wrapper or PALM.

Wed Jul 13 13:55:06 2005

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 QY 901 VAFVPCCL 907
 DB 901 VAFVPCCL 907

RESULT 6
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 Sequence 946, Application US/10295027
 Publication No. US20030232350A1
 GENERAL INFORMATION:
 APPLICANT: Afeir, Daniel
 APPLICANT: Aziz, Natasha
 APPLICANT: Giesberg, Wendy M.
 APPLICANT: Glynn, Kurt C.
 APPLICANT: Glynn, Richard
 APPLICANT: Hevel, Peter A.
 APPLICANT: Mack, David H.
 APPLICANT: Murray, Richard
 APPLICANT: Watson, Susan R.
 APPLICANT: Bob Biotechnology, Inc.
 TITLE OF INVENTION: Methods of diagnosis of cancer. Compositions and
 TITLE OF INVENTION: Methods of screening for modulators of cancer
 FILE REFERENCE: 018501-012500US
 CURRENT APPLICATION NUMBER: US/10/295,027
 CURRENT FILING DATE: 2002-11-13
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 PRIOR APPLICATION NUMBER: US 60/347,211
 PRIOR FILING DATE: 2002-01-08
 PRIOR APPLICATION NUMBER: US 60/347,349
 PRIOR FILING DATE: 2002-01-10
 PRIOR APPLICATION NUMBER: US 60/355,250
 PRIOR FILING DATE: 2002-02-08
 PRIOR APPLICATION NUMBER: US 60/356,714
 PRIOR FILING DATE: 2002-02-13
 Remaining Prior Application data removed - See File Wrapper or PAM.
 NUMBER OF SEQ ID NOS: 1386
 SOFTWARE: PatentIn Ver. 2.1
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 LENGTH: 907
 TYPE: PRT
 ORGANISM: Homo sapiens
 US-10-295-027-946

Query Match 100.0%; Score 907; DB 15; Length 907;
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 QY 901 VAFVPCCL 907
 DB 901 VAFVPCCL 907

RESULT 7
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